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| CARSTENS & CAHOON, LLP P O BOX 802334 DALLAS, TX 75380 | | | EXAMINER MACNEILL, ELIZABETH | |
| | | | ART UNIT 3767 | PAPER NUMBER |
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/726,463

Applicant(s)

HAYES ET AL.

Examiner

Elizabeth R. MacNeill

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 24 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-19,22-39 and 41-58 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-19,22-39 and 41-58 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 25-28,30,31,34-36 and 41 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Riordan et al (US 5,378,227)

O'Riordan discloses a first pump (42) for receiving a first fluid through a first delivery line (22) to a catheter (25), a second (28) pump to receive a second fluid through a second delivery line (26) separate from said first delivery line, to said catheter; a processor (36) connected to control said first and said second pumps; wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a connection point of said first and second delivery lines to said catheter. Fig 4. The first lumen (10) is prevented from co-mingling with second lumen (26) up to a connection point (at 22) which delivers fluid to the patient via catheter (25). The lumens (10) and (26) are part of the same piece of tubing (extending from 12 until 18). See paragraph spanning Col 3 and 4, showing that the two lumens are connected into one tubing.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 1-4,6-19, 22-24,42-50, are 52-58 are rejected under 35 U.S.C. 103(a) as being unpatentable over Jonsson (US 5,098,372) in view of Abbot (US 5,588,816).

Jonsson discloses a first pump (10) that is configurable to pump a first metered amount of a first fluid through a first delivery line (11) to a catheter (12); a second (19) pump that is configurable to pump a second metered amount of a second fluid through a second delivery line (Fig 2) separate from said first delivery line, to said catheter, wherein the lumen of said first delivery line and the lumen of said second delivery line remain separate up to a connection point (12) of said first and second delivery lines to said catheter.

Jonsson does not detail the controller of his device.

Abbott teaches a processor (46) connected to control first (74) and said second (76) pumps such that said second metered amount has a definable relationship to said first metered amount (abstract).

It would have been obvious to one ordinary skill in the art at the time the invention was made to use the controller of Abbott in order to make the device easier to use and to automatically adjust action the first and second pumps.

Claims 2-4,11 see Abbott Fig 2; claim 6, Jonsson 16; claim 7,55 Abbott 32; claim 8-10,12-19,43-50,56-58 Abbott Fig 1; claims 22-24,52-54 Jonsson Fig 1

5. Claims 5, 39, 51 are rejected under 35 U.S.C. 103(a) as being unpatentable over Abbott/Jonsson in view of Gillies et al. (PN 6,272,370).

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Abbott/Jonsson discloses the invention as recited in claims 1,25, 42 however, fails to disclose said pumping step pumps adenosine.

Gillies et al. teaches that it is conventional in the art for said pumping step to pump adenosine (See Column 23 Lines 51-60).

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have pumped adenosine as taught by Gillies et al. in the Abbott/Jonsson device since it would improve catheter-based administration of medicine.

6. Claims 29, 32,33,37 and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over O'Riordan in view of Abbott.

O'Riordan discloses the fluid delivery system as above, but does not disclose a heat exchanger (Abbott 31) or a controller with monitoring functions (Abbott Fig 1). It would have been obvious to one of ordinary skill in the art at the time the invention was made to use the controller and heat exchanger of Abbott in order to more precisely control the fluid infusion.

Response to Arguments

7. Applicant's arguments filed 24 September 2007 have been fully considered but they are not persuasive. Regarding O'Riordan, applicant has argued that O'Riordan does not teach delivery to the patient. See Fig 4, with the line 25 identified as "TO PATIENT". Regarding the tubing and lumens, the first lumen (10) is prevented from comingling with second lumen (26) up to a connection point (at 22) which delivers fluid to

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the patient via catheter (25). The lumens (10) and (26) are part of the same piece of tubing (extending from 12 until 18). See paragraph spanning Col 3 and 4, showing that the two lumens are connected into one tubing. The wand (10) is considered a "first fluid line" since it has a lumen for fluid. Catheter 22 delivers fluid to the patient via blood reservoir (16). Since the lumens are all connected, they are considered part of the same tubing.

8. Regarding Jonsson in view of Abbot, applicant has argued that Jonsson does not teach separate lumen of the same tubing. Again, the tubing (11), (12), and the unlabeled tubing from pump 19 are all directly connected and considered part of the same tubing. Applicant has not claimed any structure of the tubing (such as parallel lumens, lumens sharing a wall, coaxial lumens, etc) which would require the tubing to have any specific configuration other than two separate lumens which mix at a point. In response to applicant's argument that the references fail to show certain features of applicant's invention, it is noted that the features upon which applicant relies (i.e., that the second line deliver fluid at the same time as the first line delivers fluid) are not recited in the rejected claim(s). Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). Once fluid from the second line is mixed with the blood, the first pump can be reserved and delivered to the patient.

Conclusion

9. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth R. MacNeill whose telephone number is (571)-272-9970. The examiner can normally be reached on 9:00-5:30 M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Kevin Sirmons can be reached on (571) 272-4965. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

ERM

*Elizbeth
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10/24/07*

KEVIN C. SIRMONS
SUPERVISORY PATENT EXAMINER

Kevin C. Sirmons